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| 10/648,158 | 08/25/2003 | Kenneth MC Cheung | UHK.118XT | 3550 |
| 23557 7590 09/16/2010 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614 | | | | |
| | | | EXAMINER BECCIA, CHRISTOPHER J | |
| | | | ART UNIT 3775 | PAPER NUMBER |
| | | | NOTIFICATION DATE 09/16/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary

Application No.

10/648,158

Applicant(s)

CHEUNG ET AL.

Examiner

CHRISTOPHER BECCIA

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22, 28, 29, 34-39 and 41-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, 28, 29, 34-39 and 41-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed June 30, 2010, with respect to the rejection(s) of Claims 20-22, 28, 29, 34-39, 41-43, and 45-55 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 20-22, 28, 29, 34-39, 41-43, and 45-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,761,719 to *Justis et al.* in view of U.S. Patent No. 5,290,289 to *Sanders*. in further view of NPL to Shape Memory Alloys (http://www.shape-memory-alloys.com/data_nitinol.htm#bodytemperature).

As to **Claims 20, 36, 37, and 46**, *Justis* discloses a method for correcting spinal deformities in a human patient (Col. 2, Lines 37-41), the method comprising:

providing a correction device comprising an elongated rod (302), the elongated rod having a pre-contoured shape of a normal degree of kyphosis and lordosis of at least a portion of the patient's spine (Col. 12, Lines 16-19);

deforming the elongated rod to conform to a deformed portion of the patient's spine (Col. 12, Lines 22-26);

mounting the deformed elongated rod to the patient's spine including the deformed portion (Col. 12, Lines 22-38), whereby the deformed elongated rod is capable of applying a correction force having a predetermined amount to correct the deformed portion of the patient's spine;

maintaining the correction force at the predetermined amount until the deformed elongated rod resumes the pre-contoured shape to fully or substantially fully correct the spinal deformities (Col. 12, Lines 38-67 – Col. 13, Lines 1-21);

wherein the correction force is constant or substantially constant and controllable during spinal deformity correction (Col. 13, Lines 5-17), and wherein the spinal deformity is a deformity of scoliosis, kyphosis, or lordosis (Col. 2, Lines 10-31);

As to **Claims 21 and 38**, *Justis* discloses a method wherein the predetermined amount of the correction force can be adjusted (Col. 13, Lines 17-20).

As to **Claims 22 and 39**, *Justis* discloses a method wherein the correction force is activated during the spine correction surgery (Col. 12, Lines 16-38).

As to **Claim 28**, *Justis* discloses a method wherein the correction force is applied to the deformed spine portion from the anterior aspect of the spine (Col. 11, Lines 47-51).

As to **Claim 29**, *Justis* discloses a method wherein the correction force is applied to the deformed spine portion from the posterior aspect of the spine (Col. 11, Lines 47-51).

As to **Claims 34 and 41**, *Justis* discloses a method further comprising limiting the correction device from movement (Col. 12, Lines 61-66).

As to **Claims 35 and 42**, *Justis* discloses a method further comprising limiting the correction device from a rotation movement (Col. 12, Lines 46-50 and Col. 12, Lines 61-66).

As to **Claim 43**, *Justis* discloses a method further comprising providing an anchor member (304) for mounting the supporting member to the deformed spine portion (Col. 11, Lines 52-67).

As to **Claims 47-49**, *Justis* discloses a method wherein the correction force is not remotely activated (Col. 12, Lines 39-60).

As to **Claim 50**, *Justis* discloses a method wherein deforming the elongated rod comprising bending the elongated member to conform to the deformed portion of the patient's spine (Col. 12, Lines 15-38).

As to **Claim 51**, *Justis* discloses a method wherein applying the correction force comprising bending the supporting member to conform to the deformed portion of the patient's spine and mounting the bent supporting member to the patient's spine including the deformed portion (Col. 12, Lines 15-38).

As to **Claim 52**, *Justis* discloses a method wherein applying a supporting member comprising bending the supporting member to conform to the deformed spinal portion of the recipient and mounting the bent supporting member to the recipient's spine including the deformed spinal portion (Col. 12, Lines 15-38).

As to **Claims 20-22, 28, 29, 34-39, 41-43, and 45-55**, *Justis* discloses the claimed invention except for the elongated rod comprising a superelastic material having a transition temperature (A_f) within the range of human body temperature; the

correction force being generated by the superelastic material at the patient's body temperature and in an austenite phase of the superelastic material; wherein the elongated rod is deformed before or simultaneously when the elongated rod is mounted to the patient's spine including the deformed portion; and wherein the elongated rod is deformed by an orthopedic surgeon during an orthopedic procedure in order to allow the easy technical insertion of an implant for correcting scoliosis by deforming the implant to match the shape of the patient's spine.

NPL to Shape Memory Alloys discloses a superelastic material having a transition temperature (A_f) within the range of human body temperature (See Body-Temperature Ni-Ti alloy); the correction force being generated by the superelastic material at the patient's body temperature and in an austenite phase of the superelastic material (See Body-Temperature Ni-Ti alloy) in order to provide a material that can undergo correction force when exposed to normal body temperature.

Sanders discloses a method of correcting spinal deformities wherein the elongated rod is deformed before or simultaneously when the elongated rod is mounted to the patient's spine including the deformed portion (Col. 2, Lines 57-60, Col. 4, Lines 25-47); and wherein the elongated rod is deformed by an orthopedic surgeon during an orthopedic procedure (Col. 4, Lines 25-47) in order to allow the easy technical insertion of an implant for correcting scoliosis by deforming the implant to match the shape of the patient's spine, and where the rod moves to its ideal shape to the degree that the spine can withstand without risking neural damage (Col. 2, Lines 57-60 and Col. 4, Lines 13-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of providing a substantially constant force for correcting spinal deformities of *Justis* with the deforming of the elongated rod to conform to a deformed portion of a patient's spine modification of *Sanders* and Body-Temperature nitinol of NPL to Shape Memory Alloys in order to provide fusionless correction of scoliosis, using a compatible biomaterial for implantation into the spine, and to provide a material that can undergo correction force when exposed to normal body temperature.

2. **Claim 44** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,761,719 to *Justis et al.* in view of U.S. Patent No. 5,290,289 to *Sanders* in further view of NPL to Shape Memory Alloys and further in view of U.S. Patent No. 6,296,643 to *Hopf et al.*

As to **Claim 44**, *Justis* in view of *Sanders* and NPL disclose the claimed invention except for wherein the anchor member comprises a superelastic material.

Hopf discloses a spine stabilization device wherein the anchor member comprises a superelastic material (Col. 3, Lines 40-46, Col. 4, Lines 47-61, Col. 6, Lines 5-19) in order to provide fusionless correction of scoliosis, using a compatible biomaterial for implantation into the spine (Col. 6, Lines 5-11, Col. 3, Lines 40-46).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of providing a substantially constant force for correcting spinal deformities of *Justis* with the anchor members comprised of

superelastic material of *Hopf* in order to provide fusionless correction of scoliosis, using a compatible biomaterial for implantation into the spine.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775